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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,688	02/03/2005	Shuichi Matsumura	122627	8515

25944 7590 11/29/2007

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EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,688	MATSUMURA, SHUICHI	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-50* is/are pending in the application.

4a) Of the above claim(s) *47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-46 and 49* is/are rejected.

7)☒ Claim(s) *50* is/are objected to.

8)☐ Claim(s) *47 and 48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of an amendment filed September 28, 2007.

2. Claims 41-50 are now pending in this application.

Claims 1-40 have been cancelled.

Claims 41, 45 and 49 are drawn to the elected species in accordance with the prior election of March 23, 2007:

> "1. the polylactic acid is depolymerized in the presence of a hydrolase in an organic solvent;
> 2. the polylactic acid is poly(DL-lactic acid);
> 3. the hydrolase is lipase.
>
> with traverse. At least claims 1, 5, and 9 read on the elected species. "

The election of species with respect to DL-lactic acid and L-lactic acid has been withdrawn. Also, claim 42 pertaining to supercritical fluid was included in the previous office action. Thus, claims 41, 42, 43, 44 , 45, 46 and 49 are drawn to the original election.

Claims 47 and 48 have been withdrawn.

3. The rejection of the claims under 35 U.S.C. 112, first paragraph has been withdrawn.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams [Reference No 9 IDS 2-3-2005].

Williams discloses in column 2 on page 5:

> "Any degradation of polylactic acid powder to give lactic acid or its oligomers in solution should be accompanied by a lowering of the pH and this was monitored with a pH meter."

Williams discloses in column 1 on page 6:

> " Ficin: " This suggests that ficin is slow-acting and produces oligomers of lactic acid possibly retained ...." .

Williams also discloses that the pH for Ficin had the largest drop in the pH which supports the above degradation of polylactic acid to form oligomers which produces an oligomer of lactic acid. It is also noted that ficin is classified under the broad heading of hydrolase.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

However, further in light of the Supreme Court's recent decision in KSR International Co. v. Teleflex Inc (TFX)., 82 USPQ2d 1385 (2007) based on the reasoning may still include the established Court of Appeals for the Federal Circuit standard that a claimed invention may be obvious if the examiner identifies a prior art teaching, suggestion, or motivation (TSM) to make it, however, the Guidelines explain that there is no requirement that patent examiners use the TSM approach in order to make a proper obviousness rejection. Furthermore, the Guidelines point out that even if the TSM approach cannot be applied to a claimed invention, that invention may still be found obvious.

A. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams which disclosure is with poly-L-lactic acid. The reference does not disclose poly- LD –lactic acid.

If there are any differences with respect to the specific polylactic acid, this difference would have been prima facie obvious absent unexpected or unobvious patentable processes or results. It would have been reasonable for one of ordinary skilled in the art having the references in front of this skilled worker to reasonable expect that the reference would have been obvious based on the disclosure that the racemic mixture would also produce oligomers with Ficin.

B. Claims 42, 44, 46 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuichi.

The reference teaches the depolymerization of polymers with supercritical carbon dioxide at suitable temperature in the presence of a hydrolase which the reference states:

> The oligomer and the monomer which are furthermore obtained by depolymerization can reproduce the polymer of a basis by the re-polymerization.

The reference recites polyester polymers and hydroxycarboxylic acid which disclosure to one of ordinary skilled in the art render prima facie obvious to include polylactic acid to produce the oligomers which can as recited above to reproduce the polymer.

6. Claim 49 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. **No claim is allowed.**

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit **1657**
November 17, 2007

Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657